UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

Outsourcing Facilities Association, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendants, and Eli Lilly and Company, Intervenor-Defendant.	Case No. 4:24-cv-00953-P

NOTICE OF FILING OF CERTIFIED INDEX TO ADMINISTRATIVE RECORD

Consistent with the Court's January 14, 2025 Order, ECF No. 62, Defendants respectfully submit the attached certified index to the administrative record in this matter.

DATED: FEB. 4, 2025

Respectfully submitted,

/s/ Kimberly R. Stephens

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

February 4, 2025

/s/ Kimberly R. Stephens
KIMBERLY R. STEPHENS

CERTIFICATE

Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that Robert Herrell, Lead Regulatory Counsel, Division of Information Disclosure Policy, Office of Regulatory Policy, Center for Drug Evaluation and Research, United States Food and Drug Administration, whose Declaration is attached, has custody of the records relating to human drugs on file with the United States Food and Drug Administration.

In witness whereof, I have, pursuant to the provisions of Title 42, United States Code, Section 3505, and FDA Staff Manual Guide 1410.23, hereto set my hand and cause the seal of the Department of Health and Human Services to be affixed this 4th Day of February, 2025.

Howard R. Philips

Howard R. Philips
Director
Division of Information Disclosure Policy
Office of Regulatory Policy
Center for Drug Evaluation and Research
United States Food and Drug Administration

By Direction of the Secretary of Health and Human Services

DECLARATION OF ROBERT HERRELL

Robert Herrell declares as follows.

1. I am a Lead Regulatory Counsel in the Division of Information Disclosure Policy, Office of Regulatory Policy, Center for Drug Evaluation and Research, United States Food and Drug Administration ("FDA").

2. In that capacity, I have custody of records relating to human drugs on file with FDA.

3. Attached is a copy of the index of administrative record for *Outsourcing Facilities Ass'n, et al. v. FDA, et al.*, No. 4:24-cv-953 (N.D. Tex).

4. Copies of documents listed in the attached index are official records of FDA.

I declare under penalty of perjury that the forgoing is true and correct.

Executed on: February 4th, 2025

Robert R. Herrell -S

Digitally signed by Robert R. Herrell -S
Date: 2025.02.04 09:36:15 -05'00'

Robert Herrell

Index of Administrative Record for
***Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953 (N.D. Tex.)**

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Memorandum from CDR Robert Kosko, Consultant, CDER Drug Shortage Staff (DSS), through Valerie Jensen, R.Ph., Associate Director, CDER Drug Shortages Staff, to CDER Drug Shortage File, *Resolution of Tirzepatide Injection Product Shortage and Supply Status*	12/19/2024	FDA 000013-000044
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III. Information Provided by Eli Lilly and Company (Lilly)		
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Letter from Lilly to CDER Director, *Mounjaro® and Zepbound® Supply Update*	8/8/2024	FDA 000259-000260
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Email from Leah Downer, Lilly, to CDER DSS, *Shortage Website Posting Update Request - Eli Lilly and Co.*	8/16/2024	FDA 000272-000273
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Email from Patty Donnelly, Lilly, to CDER DSS, *Shortage Website Posting Update Request - Eli Lilly and Co.*	8/21/2024	FDA 000276-000285

[1] For email attachments, this "Date" column contains the date of the email that included the attachment. Many such attachments contain different dates in their file names, as shown in the "Description" column.

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Attachment "FDA TZP Supplemental Submission Outlook_23Aug2024"	8/23/2024	FDA 000307-000313
Email from Patty Donnelly, Lilly, to CDER DSS, *Tirzepatide Submission Plans Meeting Request*	8/27/2024	FDA 000314-000315
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Email from Leah Downer, Lilly, to CDER DSS, *Shortage Website Posting Update Request - Eli Lilly and Co.*	9/3/2024	FDA 000319-000320
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Attachment "TZP-US-Cover-Letter-Concord-Add." (Letter from Sally Anliker, Lilly, to CDER Division of Diabetes, Lipid Disorders, and Obesity, *Chemistry, Manufacturing, and Controls – Prior Approval Supplement*, 9/5/2024)	9/6/2024	FDA 000324-000325
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Letter from Lilly to Francis Godwin, Director, Office of Manufacturing Quality, CDER Compliance, *Compounded Tirzepatide Contaminated with Bacteria*	11/5/2024	FDA 000418-000421
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Email from Sean Griffin, Sidley Austin LLP, on behalf of Lilly, *Mounjaro® and Zepbound®*	12/6/2024	FDA 000493
Attachment "DSS Letter Compiled with exhibits"	12/6/2024	FDA 000494-000567
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FAERS report 24417477, RCT-1262376	10/8/2024	FDA 000602-000606
V. Other Records		
Gillian Tan and Damian Garde, "Lilly CEO Says Weight-Loss Drug Will Be Off Shortage Soon," Bloomberg.com (Aug. 1, 2024)	8/1/2024	FDA 000607-000608
Bruce Gil, "Eli Lilly CEO says Zepbound shortage could end 'very soon,'" Quartz (Aug. 1, 2024)	8/1/2024	FDA 000609-000611
Email from Scott Brunner, Alliance for Pharmacy Compounding (APC), to CDER DSS and OCQC, *Inquiry…*	8/9/2024	FDA 000612
Daniel Gilbert, "Eli Lilly ramps up its fight against imitation weight-loss drugs," Washington Post (Aug. 30, 2024)	8/30/2024	FDA 000613-000615
Email from Valerie Jensen to CDER DSS staff, *info from compounders*	9/9/2024	FDA 000616

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Memorandum from CDER DSS, through Valerie Jensen, R.Ph., Associate Director, CDER DSS, to CDER Drug Shortage File, *Supply Status of Glucagon-Like Peptide 1 (GLP-1) Receptor Agonists*	9/26/2024	FDA 000617-000618
Email from Lee Rosebush to CDER DSS and OCQC, *Shortage*	10/2/2024	FDA 000619-000620
Article referenced in email, "Port strike fallout"	10/2/2024	FDA 000621-000630
Email from Mark D. Boesen, Boesen & Snow Law, to OCQC, *Tirzepatide Resolution*	10/2/2024	FDA 000631-000632
Attachment "FDA Drug Shortage Letter"	10/2/2024	FDA 000633
IQVIA National Sales Perspectives "TIRZEPATIDE in j_Oct-03-2024 (4).xlsx"	10/3/2024	FDA 000634-000635
Letter from Scott Brunner, APC, to OCQC, *Off Ramp for Compounding Shortage Drugs* (docket no. FDA-2015-N-0030, document ID FDA-2015-N-0030-8519)	10/3/2024	FDA 000636-000637
Email from Andrew Van Ostrand, Vice President, Policy & Regulatory Affairs, Hims & Hers, to CDER DSS, *updated GLP-1 shortage data, Hims & Hers*	10/3/2024	FDA 000638
Email from Devta Kidd to Ombudsman and others, *FDA Compounding Decision Causing Disruption of Medical Care*	10/3/2024	FDA 000639-000642
"Template" email from Denise A Kirk to CDER DDI and Ombudsman, *Make Compound Available - there's still a shortage of Zepbound*	10/3/2024	FDA 000643000644
Email from Philip E. M. Crooker, Pistevo Law LLC, to CDER Compliance, *FDA Enforcement Discretion Related to Longshoremen Strike - Request for Consideration*	10/3/2024	FDA 000645-000646
Email from Scott Brunner, APC, to CDER DSS and OCQC, *Request for briefing: Patient impacts of tirzepatide shortage resolution*	10/4/2024	FDA 000647-000648
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Email from Scott Brunner, APC, *LETTER: Follow up on tirzepatide resolution and questions*	10/7/2024	FDA 000651-000652
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Email from Andrew Van Ostrand, *Hims & Hers Health, Sept. 2024, Weekly GLP-1 shortage data*	10/8/2024	FDA 000655-000656
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Email from Hims, *Hims & Hers Health, Week of Oct 6. 2024, Weekly GLP-1 shortage data*	10/15/2024	FDA 000694
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Article referenced in email, "It's not right.' Califf slams pharma over weight loss drug prices," Endpoints News (10/22/2024)	10/23/2024	FDA 000704-000705
Email from Marc Wagner, Baker Hostetler, to CDER DSS, *Patient reported shortages of FDA-approved tirzepatide*	10/23/2024	FDA 000706-000707
Attachment "Tirzepatide Shortage Reporting Form Redacted"	10/23/2024	FDA 000708-000709
Attachment "APC Tirzepatide Is Still in Shortage"	10/23/2024	FDA 000710-000713
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Email from Lee Rosebush, *Tirzepatide*	10/30/2024	FDA 000735-000736
Attachment "Eli Lilly - Knockoff weight loss drugs are having a moment"	10/30/2024	FDA 000737-000748
Lilly News Release, *Lilly reports Q3 2024 financial results highlighted by strong volume-driven revenue growth from New Products*	10/30/2024	FDA 000749-000755
Email from Lee Rosebush, *Record*	11/4/2024	FDA 000756

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Article referenced in email, "Americans hungry for weight-loss drugs grapple with supply and insurance hurdles," Reuters	11/4/2024	FDA 000757-759
Novo Nordisk company announcement, *Financial report for the period 1 January 2024 to 30 September 2024, Novo Nordisk's sales increased by 23% in Danish kroner and by 24% at constant exchange rates to DKK 204.7 billion in the first nine months of 2024*	11/6/2024	FDA 000760-000793
Email from Lee Rosebush, *Novo's CEO Makes Statement Today*	11/6/2024	FDA 000794-000795
Article referenced in email, "Novo Nordisk CEO on Wegovy prices, supplies and compounding," Reuters	11/6/2024	FDA 000796-000798
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Letter from Bendin, Sumrall & Ladner, LLC, *Response in Opposition to Eli Lilly's Nomination of Tirzepatide to Drug Products that Present Demonstrable Difficulties for Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act Docket No. FDA-2017-N-2562* (received 11/14/2024 in docket no. FDA-2017-N-2562, document ID FDA-2017-N-2562-0031)	11/7/2024	FDA 000815-000819
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Hims & Hers, *Americans Continue to Struggle to Access Branded GLP-1s as Shortages Continue*, https://investors.hims.com/news/news-details/2024/Americans-Continue-to-Struggle-to-Access-Branded-GLP-1s-as-Shortages-Continue/default.aspx	11/13/2024	FDA 000838-000840
Hims & Hers, "Newsroom 1113 GLP1 Supply Tracker Press Release.pdf"	11/13/2024	FDA 000841
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Email from Hims and Hers, *Hims & Hers Health, Week of Oct 6. 2024, Weekly GLP-1 shortage data*	12/9/2024	FDA 000906-000908
Attachment "GLP1 Shortage Responses_20241124"	12/9/2024	FDA 000909-000911
FDA Warning Letter to Veronvy, December 10, 2024, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/veronvy-694688-12102024	12/10/2024	FDA 000912-000914
Sneha S.K., "Lilly to offer single-dose vials of weight-loss drug on telehealth platform Ro,", Reuters, (Dec. 11, 2024), available at https://www.reuters.com/business/healthcare-pharmaceuticals/telehealth-firm-ro-provide-single-dose-vials-lillys-zepbound-obesity-patients-2024-12-11	12/11/2024	FDA 000915-000916
Elaine Chen and Katie Palmer, "Eli Lilly strikes Zepbound deal with Ro, amid questions about future of compounded GLP-1s," STAT+ Pharma, Dec. 11, 2024, available at https://www.statnews.com/2024/12/11/eli-lilly-zepbound-ro-health-agreement-weight-loss/	12/11/2024	FDA 000917-000921
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Attachment "12.10 Express Scripts Pharmacy no longer taking new GLP-1 customers NCPA."	12/11/2024	FDA 000926
Attachment "12.10 Wegovy 90 day supply r WegovyWeightLoss."	12/11/2024	FDA 000927
Attachment "12.11 Petition · Protect Patients_ Demand the FDA Ensure Access to Affordable GLP-1 Medications! - United States · Change.org."	12/11/2024	FDA 000928-000929
Sydney Lupkin, "Drugmakers and pharmacists battle over who gets to make obesity drugs," NPR, updated Dec. 12, 2024, available at https://www.npr.org/sections/shots-health-news/2024/11/20/nx-s1-5178102/ozempic-semaglutide-tirzepatide-compounding-pharmacies	12/12/2024	FDA 000930-000935

[2] Pages FDA 000895-000900 intentionally left blank, as they appeared in original file download.

Description	Date	Bates Number
Email from Ben Janacek, Baker Hostetler, *FDA-approved GLP-1s Shortage*	12/13/2024	FDA 000936-000937
Attachment "12.11 Lilly to offer single-dose vials of weight-loss drug on telehealth platform Ro Reuters."	12/11/2024	FDA 000938-000939
Attachment "12.11 Ro to offer weight loss drug Zepbound vials by teaming up with Eli Lilly."	12/11/2024	FDA 000940-000944
Attachment "12.12 Drugmakers battle pharmacies over compo..."	12/12/2024	FDA 000945-000964
Attachment "12.13 Over 50% of U.S. Adults Are Eligible for Ozempic and Wegovy, But Access Remains Difficult."	12/13/2024	FDA 000965-000968
Email from Andrew Van Ostrand, Hims & Hers, *Hims & Hers Health, Inc. GLP-1 shortage data - as of 12/14/24*	12/16/2024	FDA 000969
Attachment "Hims and Hers_GLP1 Shortage_thru 12-14-24.pdf"	12/16/2024	FDA 000970-000973
Email from Ben Janacek, Baker Hostetler, *FDA-approved GLP-1 Shortages*	12/16/2024	FDA 000974-000975
Attachment "12.14 Hims and Hers_GLP1 Shortage_thru 12-14-24."	12/16/2024	FDA 000976-000979
Attachment "12.16 Petition Protect Patients Demand the FDA Ensure Access to Affordable GLP-1 Medications."	12/16/2024	FDA 000980-000981
Attachment "12-14-24 wholesalerdata."	12/16/2024	FDA 000982-001016
Outsourcing facility 2024-1 product reports	12/17/2024	FDA 001017
FDMS email FDMS Deduplication Report for FDA-2015-N-0030-0001	12/17/2024	FDA 001018
Attachment "FDA-2015-N-0030-0001."	12/17/2024	FDA 001019-001421
IQVIA, Available IQVIA Data, https://www.iqvia.com/insights/the-iqvia-institute/available-iqvia-data	12/17/2024	FDA 001422-001424
Email from APC, *Tirzepatide Shortage Information*	12/17/2024	FDA 001425-001426
Attachment "FDA letter 12-17-2024.pdf" (docket no. FDA-2015-N-0030, document ID FDA-2015-N-0030-14056)	12/17/2024	FDA 001427-001493
Hims Reporting Send Account, *Hims & Hers Health, Week of Oct 6. 2024, Weekly GLP-1 shortage data*	12/17/2024	FDA 001494-001496
Attachment "GLP1 Shortage Responses_20241201"	12/17/2024	FDA 001497-001499
Attachment "GLP1 Shortage Responses 20241208"	12/17/2024	FDA 001500-001502
Hims tracker FAQs, https://www.hims.com/weight-loss/supply-tracker	12/18/2024	FDA 001503-001507
Hers tracker FAQs, https://www.forhers.com/weight-loss/supply-tracker	12/18/2024	FDA 001508-001512
user@votervoice.net emails to CDER DSS, *Protect my access to compounded GLP-1 treatments*	12/18/2024	FDA 001513-001514
Email from Ben Janacek, Baker Hostetler, *FDA-approved GLP-1s Shortage*, 21 attachments	12/18/2024	FDA 001515-001516
Attachment "12.17 Update Ozempic supply to remain limited in 2025 Therapeutic Goods Administration (TGA)"	12/18/2024	FDA 001517

Description	Date	Bates Number
Attachment "FDA letter 12-17-2024"	12/18/2024	FDA 001518-001584
Attachment "12.18 Ozempic shortages roll on"	12/18/2024	FDA 001585-001586
Attachment "12.18 Petition Protect Patients Demand the FDA Ensure Access to Affordable GLP-1 Medications"	12/18/2024	FDA 001587-001588
Attachment "Mounjaro - Zepbound Stock 12.13.2024"	12/18/2024	FDA 001589
Attachment "Mounjaro Shortage 12.18"	12/18/2024	FDA 001590
Attachment "Mounjaro Shortage 2 12.18"	12/18/2024	FDA 001591
Attachment "Mounjaro Shortage 3 12.18"	12/18/2024	FDA 001592
Attachment "Mounjaro Shortage 4 12.18"	12/18/2024	FDA 001593
Attachment "WeGovy Shortage 12.18"	12/18/2024	FDA 001594
Attachment "WeGovy Shortage 2 12.18"	12/18/2024	FDA 001595
Attachment "Zep Mounjaro Shortage 12.18"	12/18/2024	FDA 001596
Attachment "Zep Mounjaro Shortage 12.18"	12/18/2024	FDA 001597
Attachment "Zep Mounjaro Shortage 3 12.18"	12/18/2024	FDA 001598
Attachment "Zep Mounjaro Shortage 4 12.18"	12/18/2024	FDA 001599
Attachment "Zep Mounjaro Shortage 5 12.18"	12/18/2024	FDA 001600
Attachment "Zep Mounjaro Shortage 6 12.18"	12/18/2024	FDA 001601
Attachment "Zep Mounjaro Shortage 7 12.18"	12/18/2024	FDA 001602
Attachment "Zep Shortage 2 12.18"	12/18/2024	FDA 001603
Attachment "Zep Shortage 3 12.18"	12/18/2024	FDA 001604
Attachment "Zep Shortage 4 12.18"	12/18/2024	FDA 001605-001606
VI. Agency Policy and Guidance Documents		
FDA Strategic Plan for Preventing and Mitigating Drug Shortages	October 2013	FDA 001607-001646
CDER, Manual of Policies and Procedures, Drug Shortage Management (MAPP 4190.1 Rev. 4)	January 2024	FDA 001647-001666
Draft Guidance for Industry, Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C Act	February 2024	FDA 001667-001683
Guidance for Industry: Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act	January 2018	FDA 001684-001701
Guidance for Industry: Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act	January 2017	FDA 001702-001714
Guidance for Industry: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act	January 2018	FDA 001715-001729